

This Page Is Inserted by IFW Operations
and is not a part of the Official Record

BEST AVAILABLE IMAGES

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

IMAGES ARE BEST AVAILABLE COPY.

**As rescanning documents *will not* correct images,
please do not report the images to the
Image Problem Mailbox.**



Docket No.: KCC-17,458

THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Roger Bradshaw QUINCY, III	Group No.: 3761
Serial No:	10/037,466	
Filing Date:	21 December 2001	Examiner: Catharine L. Anderson
Title:	ANTIMICROBIAL NONWOVEN WEBS FOR PERSONAL CARE ABSORBENT ARTICLES	

**DECLARATION OF ROGER B. QUINCY, III
PURSUANT TO 37 C.F.R. §1.131(a)**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Roger B. Quincy, III, declare as follows:

1. I am employed by the Kimberly-Clark Corporation. I am the sole inventor of the subject matter claimed in U.S. Patent Application Serial No. 10/037,466, entitled "ANTIMICROBIAL NONWOVEN WEBS FOR PERSONAL CARE ABSORBENT ARTICLES."

2. Prior to 06 September 2001, I conceived the idea of treating a fibrous nonwoven web with a halogenated polystyrene hydantoin in which only the amide nitrogen atoms, and not the imide nitrogen atoms, would be halogenated. Halogenated polystyrene hydantoins having chlorine atoms linked to both (amide and imide) nitrogen atoms had been shown to exhibit biocidal activity, but released unacceptable levels of free chlorine. I proposed that only partial chlorination of the polystyrene hydantoin, to fill the amide site but not the imide site, could produce a material that is more stable yet less active.

I hereby certify that this correspondence (along with any paper referred to as being attached or enclosed) is being deposited with the United States Postal Service as First Class Mail in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on

02 June 2004

02 June 2004

Date

Mary Bethum

Signature

3. Prior to 06 September 2001, I approached HaloSource Corporation ("HaloSource") with my proposal. HaloSource had previously supplied a chlorinated polystyrene hydantoin designated Poly-1-C1, believed to have chlorine linkages present on imide and amide nitrogen sites. Following my proposal, HaloSource provided me with a new version of chlorinated polystyrene hydantoin, designated Poly-1-C1, Type 2, responsive to my proposal.

4. Prior to 06 September 2001, I treated nonwoven fabric samples with Poly-1-C1, Type 2, and evaluated the samples for biocidal activity. The treated fabric samples exhibited useful levels of biocidal activity and substantially reduced levels of free chlorine emission. This work has been documented on the following pages of my laboratory notebooks, copies of which are enclosed with dates redacted:

Laboratory Notebook P-7259, page 119; and

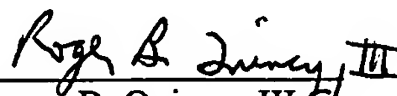
Laboratory Notebook P-7952, pages 59-62 and 69-80.

All of the foregoing notebook entries were documented prior to 06 September 2001.

5. All statements herein based on my own knowledge are true, and all statements made on information and belief are believed to be true. I acknowledge that willful false statements and the like are punishable by fine or imprisonment, or both (18 U.S.C. §1001) and may jeopardize the validity of this patent application or any patent issuing thereon.

6. Because of my unfamiliarity with the preparation of legal documents, I have been assisted in drafting this Declaration by an attorney of record, Maxwell J. Petersen.

Respectfully submitted,


Roger B. Quincy, III

Date: May 21, 2004



Corporation Serial No. P - 7259
Lab. or Department Nonwoven Technology
Project No. or Nos. _____
Date of First Entry [REDACTED]
Date of Last Entry [REDACTED]
Lab. or Dept. Head _____
Investigator Roger E. Quiney
Investigator _____
Investigator _____

LABORATORY NOTEBOOK

Treatment for Odor Control

Charged to Roger Quiney Date [REDACTED]
Signatures of Investigators

Approved By _____ UNIT MANAGER. _____ DEPARTMENT _____ DATE

TITLE *N-Halogen Chlorine Binding Idea*PROJECT NO. *57424*BOOK NO. *P-7259*From Page No. *—*

At a meeting with HaloSource at Nalco Conference Center on ~~_____~~, we were discussing the 2 chlorine binding sites on the hydantoin moiety attached to polystyrene (called polystyrene hydantoin or PSH). One of two chlorine is more labile ^{than} the other.

After the PSH has been converted to Poly-1-Cl (polystyrene N-Halogen), I asked HaloSource (Jeff Williams, et al.) if we could get a Poly-1-Cl that had only the tightly bound chlorine, then figure out a way to provide a structure with only tightly bound chlorine (no labile chlorine since this would be a product safety concern).

*R. B. Dwyer*Quincy, Roger

From: Quincy, Roger
Sent: Wednesday, ~~_____~~ 5:34 PM
To: Gadsby, Elizabeth
Subject: RE: Invention Disclosure

Thanks for the feedback. I'll think about it. I'm more interested in trying to see if the PSH can be attached to SAP and become active via a moist bleach environment. Maybe it would be best for now to document the suggestion in your minutes so we have a record of proposing the idea to HaloSource. I would expect they could use a hydantoin that has only 1 hydrogen available for conversion to Cl or Br, instead of the 2 hydrogens on their PSH. They should also be able to put electron withdrawing groups on the hydantoin adjacent to the H which might bind the chlorine more tightly. I'll have to discuss this more with Y. Liu, our resident organic chemist.

-----Original Message-----
From: Gadsby, Elizabeth
Sent: Tuesday, ~~_____~~ 4:03 PM
To: Quincy, Roger
Subject: Invention Disclosure

Roger:

As I am preparing the meeting minutes from the HaloSource meeting, I remembered the excellent idea that you had about manipulating the strength of the chlorine-binding sites. I was wondering if you wanted to consider preparing an invention disclosure on the concept. I think it is unique and HaloSource expressed that they had not been considering the needs to strengthen the bonds. It is also, a possible modification we would want to use to allow us to have improved product aging, processability, and maybe safety.

Best regards,
Elizabeth

To Page No. *—*Work done by *Roy B. Dwyer*Date ~~_____~~Witnessed *[Signature]*Recorded by *Roy B. Dwyer*Date ~~_____~~Witnessed *[Signature]*Date ~~_____~~

Proprietary. To Be Maintained in Confidence



Corporation Serial No. P-7952
Lab. or Department NT
Project No. or Nos. 57596
Date of First Entry [REDACTED]
Date of Last Entry [REDACTED]
Lab. or Dept. Head [REDACTED]
Investigator Roy B. Linsig
Investigator [REDACTED]
Investigator [REDACTED]

LABORATORY NOTEBOOK

Odor control strategies

Charged to Roy B. Linsig Date [REDACTED]
Signatures of Investigators

.....
.....
.....
.....

Approved By UNIT MANAGER DEPARTMENT DATE

TITLE Poly1-CL Type-2

From Page No. — Background: At a meeting with Helobance Corp. at Natick Conference Center on [redacted], I requested that Helobance provide K-C with a Poly1-CL (polytetrafluoroethylene-N-Helobance) that contained only tightly bound chlorine (see documentation of this idea on p. 119, P-7459). Helobance claims to have been able to reduce this idea to practice and has supplied Poly1-CL Type-2 for our evaluation.

Proposed Evaluation for Poly1-CL Type-2:

- ① Test the hypothesis about the particles with a chlorine drag tube. This will tell us if any volatile chlorine compounds are being given off by the Poly1-CL Type-2 particles. help to
- ② Test a fabric structure that contains Poly1-CL Type-2 particles with the chlorine drag tube to see if any volatile chlorine compounds are being given off.
- ③ Evaluate antimicrobial properties for a fabric structure that contains Poly1-CL Type-2 particles.

Prep of fabric structure with Poly1-CL Type-2:

— using the Wetwebbed Handsheet Form (HSF) to produce 500 gsm fluff sheet with 5% Poly1-CL Type-2 (lot H5039-77-3, rec. from Helobance 7/01) and without any Poly1-CL Type-2.

The handsheet form area is 0.258 m².
A piece of tissue lining paper was placed on top of the plate (~0.5 cm mesh size) in the HSF box. The fibrillated pulp (believed to be SW16) was divided into 4 sections (122.5 g total weight before dividing). Poly1-CL Type-2 (6.45 g) was distributed among the 4 pulp sections. The Poly1-CL Type-2 + pulp was folded like a taco and pieces were broken off and fed into the HSF head. The conditions used for the HSF were: dust collector vacuum on, vane pump on top setting (60 Hz), 40 psi pulsed air into HSF, 400 rpm blade speed (cont.)

To Page No. 60

Work done by Roy B. Ding, R. E. [redacted]

Date [redacted]

Witnessed [redacted]

Recorded by

Date [redacted]

Witnessed [redacted]

Date [redacted]

Roy B. Ding

REQUEST NO. 57596

BOOK NO. P-7952

TITLE Poly-Cell Type-2

Form Page No.

59

Conts

A Control (500 gsm fluff sheet without Poly-Cell Type-2) was made with the same HLF conditions (see p. 59, P-7952). 129 g of the fibrized pulp was used.

The two hand sheets were densified by applying a light mist of 10% H₂O₂ (diluted with H₂O) to both sides (each hand sheet has a tissue layer surrounding the pulp layer) using a spray apparatus (description can be seen on p. 143, P-6958), followed by pressing with a Carver Press (no heat) to a thickness of 0.125 inch (4 0.125 inch plates were placed between the two plates) for 5 minutes. Each of the original sheets was cut into four 9" x 9" sections to accommodate the size of the Carver press plates (~12" x 12"). Also, a piece of release paper was placed on the top and bottom of each 9" x 9" section before pressing with the Carver press. This kept the top and bottom of each section from coming in contact with the steel plates of the press. The 4 sections from each of the two hand sheets were laid out on a surface (e.g., chair) to dry overnight. The hand sheets and sections will be labeled as follows:

LabelDescription

7952-60-PA

5% Poly-Cell Type-2 / pulp hand sheet section A

7952-60-PB

" " " " " " " B

7952-60-PC

" " " " " " " C

7952-60-PD

" " " " " " " D

To Page No. 61

Work done by

Roy B. Jorgensen, R.E.H.

Date

[Redacted]

Witnessed

Witnessed

Recorded by

Roy B. Jorgensen

Date

[Redacted]

Date

[Redacted]

Proprietary. To Be Maintained in Confidence

TITLE Poly-L-Cell Type-2PROJECT NO. 57596BOOK NO. P-7952From Page No. 60Cont.LabelDescription

7952-61-CA

poly. handfect. Control section A

7952-61-CB

" " " " B

7952-61-CC

" " " " C

7952-61-CD

" " " " D

Antimicrobial Evaluation

A $\frac{1}{2}$ x $\frac{1}{2}$ piece of the following codes will be sent to Vironed Disinfectant Laboratory (down to be AppTec Laboratory Service) for ATCC method 100 (modified). Three microorganisms will be tested (*S. aureus* ATCC 6538, *E. coli* ATCC 8739, *P. mirabilis* ATCC 4630) and 5 dilutions will be done (down to 10^1 Colony forming units (CFU)).

Codes for Vironed

7952-60-PA

- PB

- PC

- PD

7952-61-CB

- CD

To Page No. 62Work done by Roy B. LingDate [redacted]Witnessed [redacted]Recorded by Roy B. LingDate [redacted]Witnessed [redacted]Date [redacted]

Proprietary. To Be Maintained in Confidence

TITLE *Poly-C Type-2*

57596
P-7452

Form Page 10 61

ViroMed letter:

 **Kimberly-Clark**

RAQ

Ms. Karen Alexander
ViroMed Biosafety Laboratories
1265-B Kennestone Circle
Marietta, GA 30066

Dear Ms. Alexander,

Please find six fabric samples (5" by 5") for microbiology test AATCC Method 100 (modified). As we discussed earlier this week, I would like to have 3 organisms (*S. aureus* ATCC 6538, *E. coli* ATCC 8739, *P. mirabilis* ATCC 4630) tested per sample using a 4 hour contact time with 5 dilutions. For reference, a similar procedure (only 4 dilutions) can be found in a previous report sent to me (Report Number: F0816018). The purchase order for this work is #15VB8653CB. Thanks for your help. Please contact me if you have any questions.

Sincerely,

Roger Quincy
Roger Quincy
Nonwoven Technology

 **Kimberly-Clark**

1400 Holcomb Bridge Road
Roswell, GA 30078-2199
(770) 587-7884
(770) 587-7703 Facsimile
E-mail: rbquincy@kcc.com

Roger B. Quincy, Ph.D.
Nonwoven Technology

Kimberly-Clark Corporation

1400 Holcomb Bridge Road Roswell, Georgia 30076 (770) 587-8000

Work done by

Roger B. Quincy

Reviewed by

Roger B. Quincy

Date

Date

Printed by: To be maintained in confidence

69

PROJECT NO. 57596
BOOK NO. P-7952

TITLE Poly 1-CE Type-2

62 Results from ViroMed

12:21 UIROMED + 7705877703

NO. 517 002



ViroMed Laboratories, Inc.

CLIENT TECHNICAL PROCEDURE

UNCONTROLLED COPY

Document #: GM210KMC.01

QA Approval: *[Signature]*

Section: General Microbiology

Technical Approval: *[Signature]*Effective Date: *[Redacted]*

Revision #: 1

Page 1 of 1

Client: Kimberly Clark

Product(s): Absorbent Fabric

Test Method: AATCC Test Method 100 (Modified)

Procedures:

Test Portion: 4-5 cm square

Container: Petri Dish

Test Organism: (1) S. aureus ATCC # 6538, (2) E. coli ATCC # 8739, (3) P. mirabilis ATCC # 4630

Inoculum level: Approximately 10^6 Time Intervals/
Incubation: 0 / NA, 4 hours / 35°C - 39°C

Diluent: Lathen Broth

Amount: 100 mL

Extraction Method/Time: Stomaching / 2 minutes

Plating and Incubation:

Aliquot or
Dilution Plated: 10^{-1} , 10^{-2} , 10^{-3} , 10^{-4} , 10^{-5}

Culture Medium: Tryptic Soy Agar

Temperature: 30°-35°C

Time: 2 days

Comments: NA

Form # GMCTP.1
Rev. 1

CONFIDENTIAL

1265-B Kennestone Circle • Marietta, GA 30066 • 866.847.6633 • 770.514.0262 • Fax 770.514.0204

Work done by ViroMed

Recorded by *Roy A. Dwyer*Date *[Redacted]*Date *[Redacted]*Witnessed *[Signature]*Witnessed *[Signature]*

Proprietary. To Be Maintained in Confidence

TITLE *Poly-U Type-2*

57596
P-7952

From Page No.

69

Cont

RBO



ViroMed Laboratories, Inc.

ViroMed's biosafety laboratories
are becoming

AppTec
LABORATORY

The report is for informational use only. It is not intended to be used for legal or regulatory purposes. The report is the property of ViroMed and its contents are confidential.

Report Number:
G0823032

Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

P.O. #: 15VB8653CB

Attn: Dr. Roger B. Quincy

GENERAL MICROBIOLOGY TEST REPORT

Sample Information: Fabric Sample, 7952-61-CD

Date Received: *[Redacted]*
Date in Test: *[Redacted]*
Date Completed: *[Redacted]*

Test Information: AATCC Method 100 (modified)
Procedure #: GM210KMC.01
Culture Medium: Tryptic Soy Agar
Neutralizer Solution: Lethen Broth

Test Sample and Organism	<i>S. aureus</i> ATCC 6538	<i>E. coli</i> ATCC 8739	<i>P. mirabilis</i> ATCC 4630
Inoculum Concentration	8.4×10^6	4.7×10^7	3.4×10^6
Initial Contact Time	1.1×10^7	4.5×10^7	3.7×10^6
4 Hour Contact Time	1.7×10^7	5.1×10^7	6.2×10^6
Percent Reduction	NR	NR	83.24%

NR = No Reduction

Katibartollett

Departmental Review

Karen Alexander

Technical Review

1265 B Kennestone Circle • Marietta, GA 30066 • 888.847.6633 • 770.514.0262 • Fax 770.514.0294

Work Done by *ViroMed*

Recorded by *Roger B. Quincy*

Date *[Redacted]*

Date *[Redacted]*

Prepared by *[Redacted]*

[Signature]

71

PROJECT NO. 57596
BOOK NO. P-7952

poly-Cl Type-2

70

Cont.

R6Q

ViroMed Laboratories, Inc.

ViroMed's biosafety laboratories
are becoming**AppTEC**
LABORATORYReport Number:
G0823029Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

P.O. #: 15VB8653CB

Attn: Dr. Roger B. Quincy

GENERAL MICROBIOLOGY TEST REPORT

Sample Information: Fabric Sample, 7952-61-CB

Date Received: [REDACTED]

Date in Test: [REDACTED]

Date Completed: [REDACTED]

Test Information:

AATCC Method 100 (modified)
Procedure #: GM210KMC.01
Culture Medium: Tryptic Soy Agar
Neutralizer Solution: Lethen Broth

Test Sample and Organism	<i>S. aureus</i> ATCC 6538	<i>E. coli</i> ATCC 8739	<i>P. mirabilis</i> ATCC 4630
Inoculum Concentration	8.4×10^6	4.7×10^7	3.4×10^8
Initial Contact Time	5.1×10^6	2.8×10^7	2.3×10^8
4 Hour Contact Time	1.3×10^7	2.9×10^7	3.1×10^8
Percent Reduction	NR	NR	86.52%

NR = No Reduction

Kate Bartlett

Departmental Review

Kare Alexander

Technical Review

1265 B Kennestone Circle • Marietta, GA 30086 • 888.847.6633 • 770.514.0262 • Fax 770.514.0294

AET

ViroMed

Roger B. Quincy

Witnessed

Witnessed

Proprietary. To be maintained in confidence.

Poly-U Type-2

71

Cont

57596
P-7952

RBA



ViroMed Laboratories, Inc.

ViroMed's biosafety laboratories
are becoming

AppTec
LABORATORY

ViroMed's biosafety laboratories are becoming AppTec Laboratories, Inc. is a leading provider of biosafety services and products. We are currently seeking qualified individuals for the following positions:

Report Number:
G0823027

Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

Attn: Dr. Roger B. Quincy

P.O. #: 15VB8653CB

GENERAL MICROBIOLOGY TEST REPORT

Sample Information: Fabric Sample, 7952-60-PD

Date Received:

Date in Test:

Date Completed:

Test Information:

AATCC Method 100 (modified)
Procedure #: GM210KMC.01
Culture Medium: Tryptic Soy Agar
Neutralizer Solution: Lethen Broth

Test Sample and Organism	<i>S. aureus</i> ATCC 8538	<i>E. coli</i> ATCC 8739	<i>P. mirabilis</i> ATCC 4630
Inoculum Concentration	8.4×10^6	4.7×10^7	3.4×10^6
Initial Contact Time	2.7×10^7	8.7×10^6	1.9×10^5
4 Hour Contact Time	3.0×10^1	1.0×10^1	5.5×10^1
Percent Reduction	99.99%	99.99%	99.97%

Katibartlett
Departmental Review

Karen Alexander
Technical Review

1265 B Kennestone Circle • Marietta, GA 30066 • 888.847.6633 • 770.514.0262 • Fax 770.514.0294

ViroMed
Roger B. Quincy

73

PROPERTY OF KIMBERLY-CLARK CORPORATION

73

TITLE Poly 1-CL Type-2

PROJECT NO. 57596

BOOK NO. P-702

72 Contd

ViroMed's biosafety laboratories
are becoming

AppTec
LABORATORY

Report Number:
G0823030

Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

P.O. #: 15VB8653CB

Attn: Dr. Roger B. Quincy

GENERAL MICROBIOLOGY TEST REPORT

Sample Information: Fabric Sample, 7952-60-PC

Date Received: [REDACTED]

Date in Test: [REDACTED]

Date Completed: [REDACTED]

Test Information:

AATCC Method 100 (modified)
Procedure #: GM210KMC.01
Culture Medium: Tryptic Soy Agar
Neutralizer Solution: Lethen Broth

Test Sample and Organism	<i>S. aureus</i> ATCC 6538	<i>E. coli</i> ATCC 8739	<i>P. mirabilis</i> ATCC 4630
Inoculum Concentration	8.4×10^6	4.7×10^7	3.4×10^8
Initial Contact Time	8.7×10^5	2.3×10^6	See Note
4 Hour Contact Time	$< 1.0 \times 10^1$	1.2×10^2	1.0×10^1
Percent Reduction	99.99%	99.99%	99.99%

Note: Due to unusually low counts for initial contact time, the inoculum concentration was used for calculation of percent reduction per client request.

Karin Barlow
Departmental Review

Karen Alexander
Technical Review

1265 B Kennestone Circle • Marietta, GA 30066 • 888.847.6633 • 770.514.0262 • Fax 770.514.0294

To Page No. 74

Work done by ViroMed

Recorded by Roger B. Quincy

Date [REDACTED]

Witnessed [REDACTED]

Date [REDACTED]

Witnessed [REDACTED]

Date [REDACTED]

Proprietary. To Be Maintained in Confidence

PROJECT NO. 57596

BOOK NO. P-7952

TITLE Poly-U Type-2

From Page No 73 Cnts

ViroMed's biosafety laboratories
are becomingAppTEC
LABORATORYThis report is confidential. No part may be used for
advertising or publicity or otherwise without written
permission. Results apply only to the materials
tested.Report Number:
G0823028Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

Attn: Dr. Roger B. Quincy

P.O. #: 15VB8653CB

GENERAL MICROBIOLOGY TEST REPORT

Sample Information: Fabric Sample, 7952-60-PB

Date Received:

Date In Test:

Date Completed:

Test Information:

AATCC Method 100 (modified)
Procedure #: GM210KMC.01
Culture Medium: Tryptic Soy Agar
Neutralizer Solution: Lethen Broth

Test Sample and Organism	<i>S. aureus</i> ATCC 6538	<i>E. coli</i> ATCC 8739	<i>P. mirabilis</i> ATCC 4630
Inoculum Concentration	8.4×10^8	4.7×10^7	3.4×10^8
Initial Contact Time	1.0×10^7	2.7×10^7	4.4×10^8
4 Hour Contact Time	5.0×10^1	3.0×10^1	2.5×10^1
Percent Reduction	99.99%	99.99%	99.99%

Kate Parbuck
Departmental Review

Karen Alexander
Technical Review

1265 B Kennestone Circle • Marietta, GA 30066 • 888.847.6633 • 770.514.0262 • Fax 770.514.0294

To Page No. 75

Work done by ViroMed

Recorded by Roger B. Quincy

Date

Date

Witnessed

Witnessed

Date

Date

Prepared To Be Maintained in Confidentiality

PROPERTY OF KIMBERLY-CLARK CORPORATION

Poly-U Type-2

PROJECT NO. 57596

BOOK NO. P-7952

74

Costs

RBB

ViroMed Laboratories, Inc.

ViroMed's biosafety laboratories
are becoming

AppTEC
LABORATORY

The ViroMed Laboratories, Inc. is a leading provider of biosafety services to the pharmaceutical and biotechnology industries. Our services include the design, construction, and operation of biosafety cabinets, isolators, and other containment equipment. We also provide training and consulting services to our clients.

Report Number:
G0823031

Kimberly-Clark
1400 Holcomb Bridge Road
Roswell, GA 30076-2199

P.O. #: 15VB8653CB

Attn: Dr. Roger B. Quincy

GENERAL MICROBIOLOGY TEST REPORT

Sample Information: Fabric Sample, 7952-60-PA

Date Received:

Date in Test:

Date Completed:

Test Information:

AATCC Method 100 (modified)
Procedure #: GM210KMC.01
Culture Medium: Tryptic Soy Agar
Neutralizer Solution: Lethen Broth

Test Sample and Organism	<i>S. aureus</i> ATCC 6538	<i>E. coli</i> ATCC 8739	<i>P. mirabilis</i> ATCC 4630
Inoculum Concentration	8.4×10^8	4.7×10^7	3.4×10^8
Initial Contact Time	1.0×10^7	2.4×10^7	1.6×10^8
4 Hour Contact Time	$< 1.0 \times 10^1$	3.3×10^1	$< 1.0 \times 10^1$
Percent Reduction	99.99%	99.99%	99.99%

Kathie Barbolet
Departmental Review

Karen Alexander
Technical Review

1265 B Kennestone Circle • Marietta, GA 30066 • 888.847.6633 • 770.514.0262 • Fax 770.514.0294

AE7

To Page No. 76

ViroMed

Roger B. Quincy

Date [Redacted]

Witnessed

Date [Redacted]

Witnessed

Proprietary. To Be Maintained in Confidence

775 Poly-Cl Type-2

75 Summary of Viroed Results:

All of the 5% Poly-Cl Type-2 / fluff samples (i.e., 7952-60-PA, PB, PC, AD
-PD) show excellent antimicrobial properties towards *S. aureus*, *E. coli*, and
P. mirabilis.

Page 2 Dring
Page 2 Dring

CE/Salji

TITLE Poly-Cl Type-2

PROJECT NO. 57596

BOOK NO. A-7952

From Page No. 76

Drage Tube Experiments to evaluate the headspace about various

Poly-Cl samples for chlorine gas.

R8Q

Cl Drage Tube Expts. for Poly-Cl samples

Sample #

Description

1A

"high Cl" Poly-Cl tested by Phil Lee (AT) and J. Brooks (AC) in

0.0509g sealed in 20cc headspace vial at 5:06p

2B

Poly-Cl w/ birds, rec 3/27/01 from J. Williams (Holtzman)

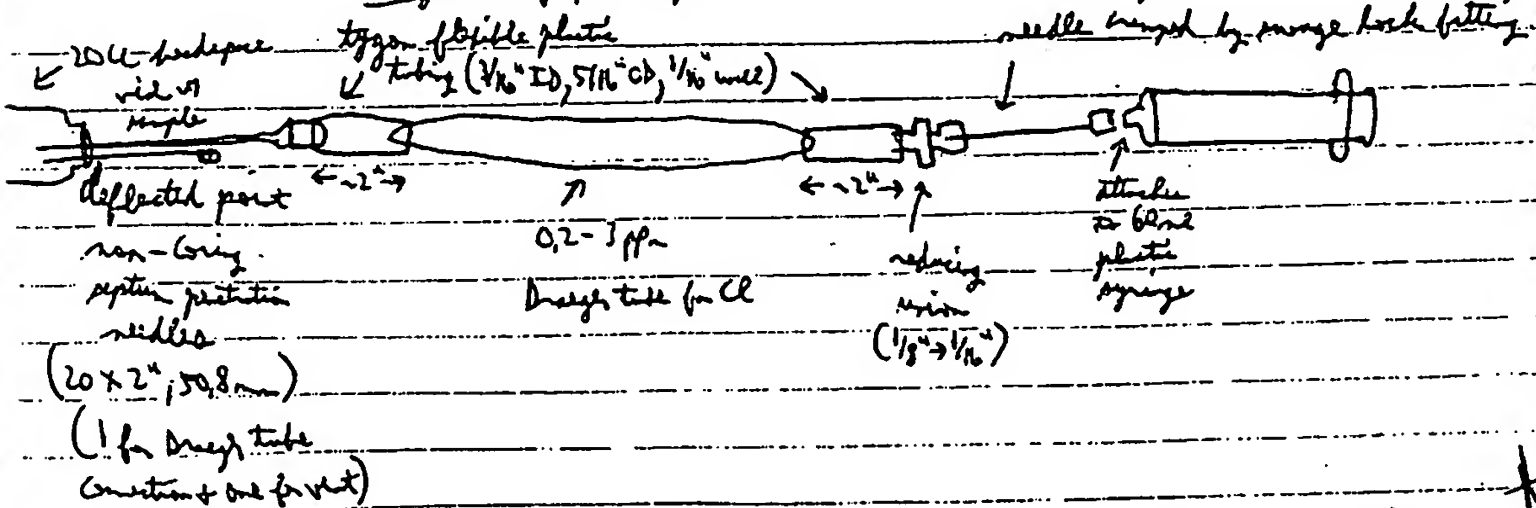
0.0499g sealed in 20cc headspace vial at 5:11p

3C

Poly-Cl before birds (AS-030-19-1), rec from J. Williams (100g) on

0.0500g sealed in 20cc headspace vial at 5:117p

Diagram of set-up



(Cont. next page)

To Page No. 78

Work done by R. Quigg, R. Borders

Recorded by Roger E. Quigg

Date

Date

Witnessed

Witnessed

Date

PROJECT NO. 57596

BOOK NO. P-7952

TITLE Poly-Cl-Type-2

From Page No. 77

Certs

Cl Drags Tube Expts. for Poly-Cl samples

Sample #	Time	60 ml volume	Comments
1A	2:07p	1	tan-brown color develops in tube to reading of 0.2 ppm. Syringe stays at 60 ml when let go (\Rightarrow no vacuum created).
	2:13p	1 more	tan-brown color to $\sim 1/2$ between 0.2 and 0.5 ppm (~ 0.4)
	2:16p	1 more	tan-brown color almost reached 0.5 ppm (~ 0.4)
	2:18p	1 more	" " " at 0.5 ppm (~ 0.4)
	2:19p	1 more	" " " betw 0.5 ppm and 1 ppm (call it 0.6 ppm) (~ 0.7 ppm)

Note: Cut new piece of tygon tubing betw sample needle and new drags tube before analyzing sample 2B.

2B	2:31p	1	tan-brown color developed rapidly and was above the 3 ppm MAX. reading after completing 60 ml stroke; syringe stays at 60 ml when let go (\Rightarrow no vacuum created).
----	-------	---	--

Note: Sample "1A" was lighter in color (less tan, more white) than sample "2B" or "3C".

3C Is this due to more Cl in samples "2B" and "3C"?

3C	2:50p	1	tan-brown color developed rapidly and was above the 3 ppm MAX. reading after completing the 60 ml stroke; syringe stays at 60 ml when let go (\Rightarrow no vacuum created).
----	-------	---	--

Note: Next test Van Gel O w/ Poly-Cl for removal of residual chlorine.

To Page No. 79

Work done by Roy B. Dwyer
 Recorded by Roy B. Dwyer

Date [redacted]Date [redacted]Witnessed [signature]Witnessed [signature]

Proprietary. To Be Maintained in Confidence

PROPERTY OF KIMBERLY-CLARK CORPORATION

TITLE Poly-Cl Type-2PROJECT NO. 57596BOOK NO. P-7952From Page No. 78Contd

██████ → Cl Dye Tube Expt for new Poly-Cl (i.e. Poly-Cl Type-2) RBR

— using Poly-Cl Type-2 (H5039-77-3, 54.3 g) → received from Halobrom

Sample #

080301-1 → 0.0521 g sealed in 20cc headspace vial at 11:11A ██████

At ~4:38p ██████ tested for Cl as follows: (Note: using same setup as described for ██████ Expt. in Wedgwood 2000 book)

<u>Time</u>	<u>band volume</u>	<u>Comments</u>
4:42p	1	no color
4:43p	1 more	no color
4:48p	1 more	" "
4:50p	1 more	" "
4:52p	1 more	maybe a v. sl trace of the yellow color had developed compared to a new tube. The color was well below the first mark of 0.2 ppm

090301-5 → 0.0501 g Poly-Cl Type-2 + 0.0485 g saline sealed in 20cc

headspace vial at 11:18A ██████. Note → This amount of saline resulted in a small amount of liquid suspending about 1/10 of the beads in the cone of the vial. The other 9/10 of the beads appeared to be fixed to the bottom of the vial, but liquid was not obvious. Did the polyethylene absorb/absorb some of the saline?

<u>Time</u>	<u>band volume</u>	<u>Comments</u>
5:02p	1	* sl yellow color has developed but below the first
5:04p	1 more	→ the sl yellow color is diffuse but about 0.2 ppm mark
5:06p	1 more	→ 1/2 way to the first mark (0.2 ppm),
5:12p	1 more	→ diffuse but almost up to the 0.2 ppm mark
5:13p	1 more	→ " " " " " " " "

Note: The beads in this vial are light yellow in color compared to the white beads in sample 080301-1.

Slit liquid is visible. * Used the same Dye Cl tube as used for sample 080301-1. (Cont. next page)

To Page No. 80Work done by Roy B. DwyerDate ██████Witnessed ██████Recorded by Roy B. DwyerDate ██████Witnessed ██████Date ██████

Proprietary. To Be Maintained in Confidence

TITLE Poly-Cl Type-2

PROJECT NO. 57596
BOOK NO. P-7952

From Page No. 79

Cont.

RBR

Cont. Cl Drug Tube Expts. for Poly-Cl Type-2

The wet syringe + syringe that were ~~not~~ connected to the drug tube assembly (assembly was removed) were left inserted into the headspace vial for 080301-S to see if any corrosion occurs (as seen for sample 3C for ~~CL~~ Cl Drug Tube Expts. → see Hedgcock-6C 2000 book).

8/16/01 more Cl Drug Tube Expts. for Poly-Cl Type-2

Sample #

081601-1 → 0.0505 g sealed in 20cc headspace vial at 4:31p

At 4:12p, put 081601-1 into GC#1 oven w/ lid closed at 50°C.

At 4:32p, connected the drug tube assembly (see diagram in Hedgcock GC-2000 book dated ~~10/1/00~~)

And pulled 8' fine 60 ml volume thru the drug tube. The tube became only v. slightly yellow-colored about 1/2 liter the first run & the first reading of 0.2 ppm. The color was not continuous; it was very diffuse (i.e. the yellow color was dispersed amongst uncolored (white) material (particles) in the tube). The Poly-Cl Type-2 particles are the same color (white to off tan white) as the original particles after being heated to 50°C and cooled to room temp.

Conclusion The new Poly-Cl (i.e. Poly-Cl Type-2) is considerably more stable in terms of releasing chlorine gases than previous versions (see pp. 77-78, P-7952). Need to work for potential instability when the Poly-Cl Type-2 comes in contact with liquid (see above results on P. 79, P-7952).

To Page No. 119

Work done by Roy B. Dwyer, R. B.
Recorded by Roy B. Dwyer

Date 8/16/01 Witnessed [Signature]
Date 8/16/01 Witnessed [Signature]

Proprietary. To Be Maintained in Confidence

TITLE Poly-Cl Type-2

PROJECT NO. 57596

BOOK NO. P-7952

From Page No. 80

More headspace chlorine data for Poly-Cl Type-2:

080301-5 → observation for 080301-5

RBG

080301-5 has had two needles submerged thru the septa into the headspace vial since ~~they~~ today these needles were removed and observed for effects of corrosion (see facing page)

AE

Conts 10/5/01 → observation for 080301-5

RBG

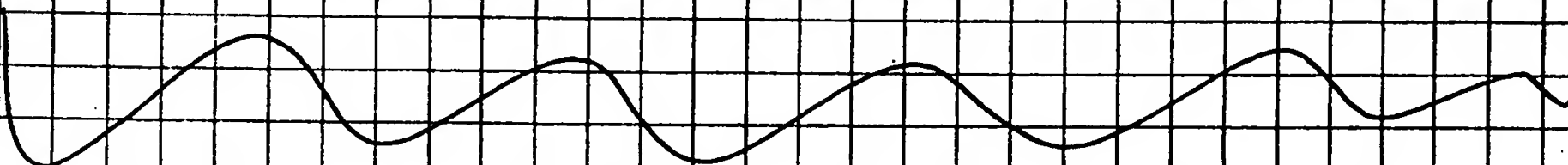
Both needles show a small spot brown in color that coincides with the part of the needle that was in the septa material. There is not any discoloration (indicative of corrosion from headspace Cl_2) on the part of the needles that was submerged inside the headspace vial (with the saline and Poly-Cl Type-2 particles).

This result is different from the previous Poly-Cl (type 1), in which a large amount of corrosion was observed for the submerged needle in the headspace vial with the Poly-Cl type 1 particles. Note → the Poly-Cl type 1 results showed lots of Cl_2 in the headspace (see Cl tray results for ~~080301-5~~).

See headspace GC book.

AE

Note: See p. 79, P-7952 for the headspace chlorine results for the 080301-5 sample.



To Page No. 120

Work done by Roy B. Juring
Recorded by Roy B. Juring

Date ~~08/03/01~~

Witnessed [Signature]

Date ~~08/03/01~~

Witnessed [Signature]

Date ~~08/03/01~~

Proprietary. To Be Maintained in Confidence

TITLE Poly-Cl Type-2PROJECT NO. 57596BOOK NO. P-7952From Page No. 119Cont.██████ → Cl. Dragg Tube Expts for Poly-Cl Type 2

RBR

██████ → ██████ → Poly-Cl Type-2 (45079-77-3, 543g) → received from Helofume aSample #101801-1 → 0.0504 g Poly-Cl Type 2 + 0.1455 g saline sealed in 20cc headspace vial at 3:59 p ██████

At 3:58 p, put 101801-1 into GC #1 oven w/ lid closed at 37°C,

At 4:27 p, Connected the Dragg Tube Assembly (see diagram in Headspace GC 2000 book dated ██████)

used new tubing, 2 needles to vial were new, and new Dragg tube
 and pulled fine 60 ml volume thru the new Dragg tube. Comparison to a fresh tube
 against a white background showed a v. slight trace (slight yellowish color
 "diffuse") next to the first mark, between the first mark and the first reading of 0.2 ml.
 This should really be considered non detectable.

101801-2 → 0.0580 g Poly-Cl Type 2 + 0.1462 g saline sealed in 20cc headspace vial at 4:03 p ██████

██████ → At 4:33 p, put 101801-2 into GC #1 oven w/ lid closed and began heating oven from
 37°C to 50°C. oven was at 50°C at 4:34 p (actually a overheat to 51°C, back to
 50°C when checked at 4:40 p)

Note: Used the same Dragg tube for this sample, but used the new needles as
 a new need for sample 101801-1.

At 4:51-4:55 p, pulled fine 60 ml volume thru the connected new Dragg tube. oven
 Comparison to a fresh tube against a white background again showed maybe top
 a v. slight trace of the yellow color just like described for tube 101801-1. was 50%

To Page No. 121

Work done by Roger B. Dering
 Recorded by Roger B. Dering

Date ██████Date ██████Witnessed ██████Witnessed ██████Date ██████Date ██████

Proprietary. To Be Maintained in Confidence

PROPERTY OF KIMBERLY-CLARK CORPORATION

PROJECT NO. 57596BOOK NO. P-7952TITLE Poly1-CI Type-2From Page No. 120Summary of all headspace-chlorine data for various Poly1-CI samples;

Quincy, Roger

From: Quincy, Roger
 Sent: Tuesday, [REDACTED] 11:25 AM
 To: Laird, Sarah; Evans, Eric; Hansen, Dick; Berrier, Phillip; Wyatt, Nancy
 Cc: Gadsby, Elizabeth; Edens, Ron; Pike, Dan; Everhart, Chene; Zabronsky, Jerry
 Subject: Poly1-CI Headspace Chlorine Data

Here are the headspace chlorine data for the various Poly1-CI samples, including the "wet, elevated temp." samples (requested from Product Safety Review Meeting). Please let me know if there is any other testing required for our requested safety clearance (for urine odor panel study)?

Poly1-CI Type-2
 Headspace Cl s...

Headspace Chlorine Results for Poly1-CIBackground:

Drager tube CH 24301 (Chlorine 0.2/a) with a standard measuring range of 0.2 to 3 ppm was used to determine headspace chlorine levels for various Poly1-CI samples. In the presence of chlorine gas (Cl_2), the tube will undergo a color change from white to yellow-orange. Bromine, chlorine dioxide, and nitrogen dioxide will also cause this color change. For an actual chlorine concentration of 0.2 to 3 ppm to be read from the tube, the requirement is for 10 strokes to be pulled through the tube using a Drager bellows type pump. Each stroke supplies 100 cm^3 . If only one stroke or 100 cm^3 is pulled through the tube, then the measuring range for the tube will be 2 to 30 ppm. For the various Poly1-CI samples, Poly1-CI powder alone and in combination with saline was placed in a 20-cm^3 headspace vial. The vial was crimped shut and left at ambient temperature for a desired length of time. Then, the vial was either tested for headspace chlorine or first placed in a GC oven at elevated temperature for a desired length of time before being tested. The headspace from the vial was tested for chlorine by piercing the septum of the vial cap with a needle that was attached to the Drager tube with rubber tubing. The headspace was removed with a 60-cm^3 syringe that was attached to the other end of the Drager tube with rubber tubing. The septum of the vial cap was also pierced with a second needle in order for ambient air to replace the removed headspace air above the sample. The amount of headspace chlorine for a sample was calculated from the Drager tube reading, the number of 60-cm^3 volumes removed, and the relationship that 1000 cm^3 (10 strokes) must be pulled through the tube in order to read chlorine in a range of 0.2 to 3 ppm.

To Page No. 122

Work done by Roger B. Juring
 Recorded by Roger B. Juring

Date [REDACTED]
 Date [REDACTED]

Witnessed [REDACTED]
 Witnessed [REDACTED]

Date [REDACTED]

Proprietary. To Be Maintained in Confidence

TITLE *Poly1-Cl Type-2*PROJECT NO. *57596*BOOK NO. *P-7952*From Page No. *121**Cont. Summary***Results:**

The following table shows the headspace chlorine data for various Poly1-Cl samples.

Sample	Details	Tube Reading	Calculated Amount	Calculated per Piece ¹
Poly1-Cl Type-1, Dry	12 days at room temp.	> 3 ppm	> 50 ppm	> 68 ppm
Poly1-Cl Type-2, Dry	6 days at room temp.	<<< 0.2 ppm	<<< 0.7 ppm	<<< 0.9 ppm
Poly1-Cl Type-2, Wet	+ 300% saline, 6 days at room temp.	< 0.2 ppm ²	< 0.7 ppm ²	< 0.9 ppm ²
Poly1-Cl Type-2, Dry, Elevated Temp.	1 day at room temp., 20 min. at 50°C	<< 0.2 ppm	<< 0.7 ppm	<< 0.9 ppm
Poly1-Cl Type-2, Wet, Elevated Temp.	+ 300% saline, 1 day at room temp., 30 min. at 37°C	<<< 0.2 ppm	<<< 0.7 ppm	<<< 0.9 ppm
Poly1-Cl Type-2, Wet, Elevated Temp.	+ 300% saline, 1 day at room temp., 20 min. at 50°C	<<< 0.2 ppm	<<< 0.7 ppm	<<< 0.9 ppm

¹ "Calculated per Piece" was determined by taking the "Calculated Amount" of chlorine, dividing by the weight of Poly1-Cl in the headspace tube (ca. 0.05 g), and then multiplying by the amount of Poly1-Cl in a 3-inch diameter piece of 600 gsm fluff that contains 2.5 wt% Poly1-Cl (0.0684 g). The urine odor panel study will use 3-inch diameter pieces of materials.

² These values were determined from a Drager tube that had been previously used for the "Poly1-Cl Type-2, Dry" sample. Therefore, the reported values are probably higher than values that would have occurred with a new tube. New tubes were used for all other samples.

To Page No. *123*Work done by *Roy & Irving*Date *[redacted]*Witnessed *[redacted]*Date *[redacted]*Recorded by *Roy & Irving*Date *[redacted]*Witnessed *[redacted]*Date *[redacted]*

Proprietary. To Be Maintained in Confidence